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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,349	09/12/2005	Atsushi Nagasawa	0230-0219PUS1	5681
2292 7590 03/02/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1794				
NOTIFICATION DATE		DELIVERY MODE		
03/02/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/520,349

**Applicant(s)**

NAGASAWA, ATSUSHI

**Examiner**

HAMID R. BADR

**Art Unit**

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20, 23-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 20, 23-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicants' amendment filed 12/11/2009 is acknowledged.

Rejection of claims 20, and 23-24 under 35 USC § 112 first paragraph is withdrawn due to deposit being made under the Budapest Treaty. A copy of this certificate is on file.

Claims 20 and 23-24 are being considered on the merits.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nakagawa et al. (1994, Construction from a single parent of baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1).
3. R1 studies the hybridization of spores of *Saccharomyces cerevisiae* (commercial baker's yeast) to construct a baker's yeast which is freeze-tolerant and has fermentative activity in both lean and sweet doughs (Abstract).
4. R1 teaches determining the mating types to be used for their hybridization process (Page 3500, Col. 1, Determination of mating type).

5. R1 discloses the process of construction of hybrids. The isolated haploid strains showing opposite mating types are crossed by mixing in liquid medium. After the hybridization process, isolated strains are checked for their sporulation ability. Spore forming isolates are considered hybrids. (Page 3500, Col. 1, construction of hybrids)
6. R1 gives details of dough ingredients for lean, regular and sweet doughs. A commercial hard wheat flour is used having 12% protein and 0.36% ash (Page 3500, Col. 1 ingredients of doughs and Table 1).
7. Given that R1 discloses the suitability of the developed strain of yeast for lean, regular and sweet doughs, it is clear that the fermentability of such doughs will be in the same range as presently claimed.
8. R1 teaches the dough raising test by measuring the carbon dioxide evolved after 2 hours at 30°C. (Page 3500, Col.1 dough raising test)
9. R1 explains the frozen dough system where the prepared doughs are stored at -20°C for 1 week. After the freezing period, the thawed dough is placed in a bottle of Fermograph and the dough raising activity is measured for 2 hours. (Page 3500, Col. 1 Frozen dough system)
10. R1 indicates that it is possible to obtain strains with more improved qualities such as leavening ability and freeze tolerance than the commercial baker's yeast now available. (Page 3502, Col. 1, lines 13-17)
11. R1 is silent regarding *Saccharomyces cerevisiae* strain FT-4 (FERM BP-8081).
1. R1 discloses the construction of a baker's yeast, *Saccharomyces cerevisiae*, which has high freeze tolerance, and high fermentative activity in both lean and sweet

doughs. Paragraphs 4-7 above, summarize the hybridization process for creating the new strain of baker's yeast which is both freeze and high sugar tolerant. Furthermore, the use of *Saccharomyces cerevisiae* as baker's yeast, its incorporation into bread dough and baking the dough to produce a baked product such as bread, as presently claimed, is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to create a strain of baker's yeast to be freeze and high sugar tolerant as disclosed by R1. One would do so to create a baker's yeast which can maintain its fermentative ability after the dough is thawed from a frozen state. Such a yeast would be useful in formulations of high sugar content. Absent any evidence and based on the teachings of the cited reference, there would be a reasonable expectation of success in developing such strain of baker's yeast. Although R1 does not disclose the same process, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed strain and given that R1 meets the requirements of the claimed *Saccharomyces cerevisiae*, R1 clearly meet the requirements of present claims.

***Response to Arguments***

Applicant's arguments have been thoroughly reviewed. They are not deemed persuasive for the following reasons.

1. Applicants argue that Nakagawa is completely silent about the isobutyric acid content of the developed yeast strains.
  - a. It should be realized that isobutyric acid is one the metabolites produced by yeast during the fermentation of dough. Therefore, the presence of this compound in the fermenting dough is inherent in the baker's yeast.
  - b. The baker's yeast (*S. cerevisiae*) disclosed by R1 has the attributes of low temperature tolerance and high sugar tolerance. It is also agreed that R1 is silent regarding the isobutyric acid content. However, there is no evidence to indicate that the isobutyric content of the yeast disclosed by R1 is more than the isobutyric content of the developed strain by the Applicants.

Further, the isobutyric acid is a volatile acid and as such it does not withstand the high baking temperatures. Again there is no evidence regarding the presence of isobutyric acid in baked goods and the consequences, of having more that certain levels, on the organoleptic properties of baked products.

Further, isobutyric acid has been implicated to be one of the compounds in the generation of the flavor of baked products. For instance please see Plomp US 5,916,609 Col. 5, lines 32-40.

It is noted that volatile fatty acids such as isobutyric acid have been investigated for their effect on the taste and aroma of wines and they may play a role in wine making. Moreover, such a volatile acid may affect the taste of yeast extract prepared from yeasts of higher isobutyric acid content.

While the data in Table 3 (page 16 instant specification) clearly show the difference between strain FT-4 and other commercial baker's yeasts regarding the isobutyric acid content, their significance on the taste and aroma of baked goods is lacking. The applicants compared bread doughs made with different yeasts for offensive taste and odor. It is not even clear what is regarded as offensive taste and odor to Applicants is really offensive to others. Fig. 2 of the instant specification compares the doughs and not the baked product. There is no evidence to suggest that the use of FT-4 strain in the dough results in improved taste and aroma of the baked product.

Given the volatility of isobutyric acid at baking temperatures, it does not seem to play an important role in the taste and aroma of the final baked product.

In wine making art, the fermentation of must containing abundant sugar leads to wine with lower fatty acid concentration including isobutyric acid. Therefore, the adaptation to high sugar environments through hybridization and/or recombinant technology may have the isobutyric acid lowering effect.

2. Applicants argue that the dough made with their developed strain has high fermentability after prolonged frozen storage and that Nakagawa's strain is stored at -20C only for one week.
  - a. It is agreed that Nakagawa presents data for doughs stored at freezing temperatures after one week of storage. However, the Nakagawa's strain has been developed to be freeze tolerant. Having such a property, being stable after prolonged frozen storage is inherent in the developed strain.
3. Applicants argue that Nakagawa is silent regarding yeast taste and that the presently claimed yeast is tasteless and odorless due to the low isobutyric acid content.
  - a. It should be realized that the data presented by the Applicants, regarding the taste and odor, concerns the dough not the baked product. Raw dough is not normally consumed so that its flavor be of any concern. For baked products, the natural isobutyric acid metabolite should not be causing any problems.  
  
Many yeast metabolites are formed which beneficially affect taste and aroma of bread products. Isobutyric acid has been noted to possess that property. (Please see Plomp, US 5,916, 609; col. 5, lines 32-40).

### ***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr  
Examiner  
Art Unit 1794

/Keith D. Hendricks/  
Supervisory Patent Examiner, Art Unit 1794